(12) UK Patent Application (19) GB (11) 2 370 777 (13) A

(43) Date of A Publication 10.07.2002

(21) Application No 0100346.6

(22) Date of Filing 06.01.2001

(71) Applicant(s)
Roozbeh Shirandami
Flat 5, 28 Cintra Park, Upper Norwood, LONDON, SE19 2LH, United Kingdom

(72) Inventor(s)
Roozbeh Shirandami

(74) Agent and/or Address for Service
Roozbeh Shirandami
Flat 5, 28 Cintra Park, Upper Norwood, LONDON, SE19 2LH, United Kingdom

(51) INT CL[7]
A61L 27/48 27/44 27/56 27/58

(52) UK CL (Edition T)
A5R RAG

(56) Documents Cited
EP 0277678 A **EP 0204931 A**
EP 0146398 A

(58) Field of Search
UK CL (Edition S) **A5R RAG**
INT CL[7] **A61L 27/44 27/48 27/56 27/58**
ONLINE:EPODOC, WPI, JAPIO, CHEMABS, MEDLINE, BIOSIS

(54) Abstract Title
Biodegradable tissue scaffold and bone template

(57) A bioabsorbable composite prosthesis formed by fibre reinforcement of a bioabsorbable polymer matrix (1) by means of bioabsorbable hollow fibres (2) to form a porous composite prosthetic device, wherein the bioabsorbable polymer matrix preferably has a degradation rate greater or equal to the bioabsorbable hollow fibre. The prosthesis may have a continuous or discontinuous pore structure depending on the length of the hollow fibres. The fibres may be coated by an osteo-conductive material such as hydroxyapitite of filled with bio-active substance such as a growth factor, hormone or therapeutic agent. The fibres may also have a porous wall. In a preferred embodiments, the prosthesis may take the form of an intramedullary device or a scaffold to repair damaged cartilage.

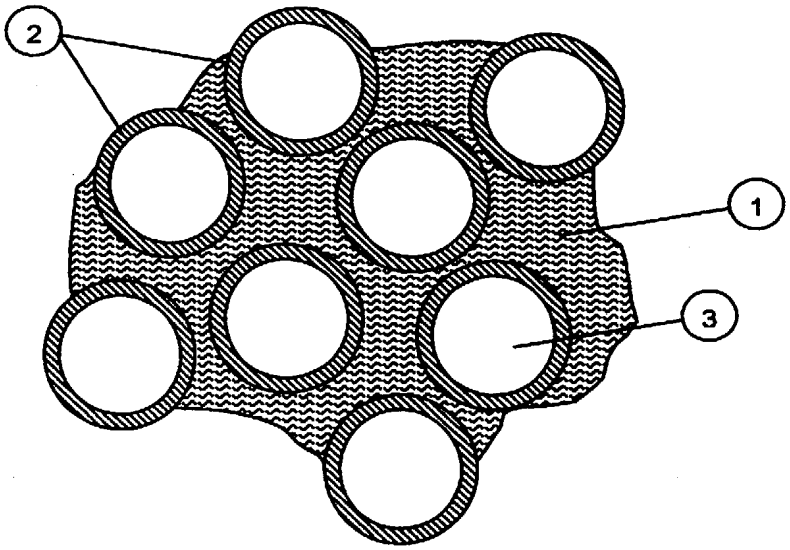

Figure 1

GB 2 370 777 A

Figure 2 is a perspective view of intramedullary prosthesis for internal fracture fixation of long bones and in particular fractured hip.

Figure 3 is the sectional view of the intramedullary prosthesis along its long axis showing the preferred arrangement of fibres for the nail and the spacer ring.

Figure 4 is the cross sectional view of the intramedullary prosthesis at the position of the spacer ring along A-A as shown in Fig.2.

Figure 5 is the perspective view of the proposed prosthesis used for resurfacing of a damaged cartilage at a joint.

While the invention is susceptible to various modifications and alternative forms, specific embodiment thereof has been shown by way of examples. It should be understood that the examples and drawings are not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling with in the spirit and scope of the invention as defined by the pending claims.

Turning to figure 1, the biodegradable prosthetic device constructed in accordance with the present invention, is manufactured from biodegradable polymers matrix (1) having Young's modulus E_m, reinforced by means of biodegradable hollow fibres (2) having Young's modulus E_f and cross sectional area A_f, to form a porous composite formed by the pores (3) with pore area A_p. To compensate the loss of stiffness and strength due to the porosity, in a preferred embodiment the reinforcing fibres are chosen such that its Young's modulus and strength is greater than or equal to the biodegradable polymer matrix such that $E_f A_f \geq E_m A_p$. This means that there is no loss of elastic properties as a result of pores, since their contribution to the mechanical properties is replaced by the elastic properties of the fibre.

Like other fibre reinforced composites, the strength and stiffness and the proposed composite prosthetic template can now be controlled is controlled by the volume fraction of the fibre reinforcement, orientation and form of fibre

component of the said composite, the density, orientation and nature of the pores (i.e. whether continuous or discrete) can now be controlled by means of volume fraction, fibre orientation and type of reinforcement (i.e. long or short fibre) respectively.

The prosthetic templates formed by the present invention are biodegradable which are either absorbed into the body or eliminated by other natural process from the body. Composite biodegradable device can now be designed by using simple design rules that have been developed for composite materials (i.e. rule of mixtures, see for example: An introduction to composite materials by Derek Hall).

As with all composite parts the fibre length (i. e discrete or substantially long) has an important effect on the structural performance of the component as well as the manufacturing route for the component. Similarly, the proposed biodegradable composite device may be reinforced by means of either short or long hollow fibres depending on the end use. Where, the proposed biodegradable device is to form laminar (i.e. plate like) or linear component (i.e. long section of uniform cross-section) the composite device may be reinforced by means of substantially long fibres. In most cases however, composite prosthetic devices manufactured by these methods will require secondary shaping processes (see for example US 4,902,297). Where three-dimensional continuous pores are required, the component may be manufactured from pre-formed three-dimensional fibre reinforcement that is over moulded by matrix in a resin transfer moulding. An Alternative is to use short fibre reinforcement using moulding processes such as injection moulding.

Advances in injection moulding process (e.g. GB 217042B, Bevis et. al. now marketed under the name SCORIM) have made possible the control of fibre orientation during the moulding operation. It has also been shown that the use of process such as described in GB 2170142B, will result in not only orientation of the reinforcing fibres but also alignment of polymer molecular

chain, resulting in the self reinforcement and hence mechanical characteristics of the polymer in the desired direction.

The matrix of the aforementioned composite polymer may be chosen from a wide range of biodegradable polymers including synthetic polymers, copolymers, and polymer alloys as well naturally based polymers such as destructured natural starch (EP 992 251 A1, de Bruijn et. al.). The reinforcing component may be chosen from bioactive ceramics such as absorbable bioactive glass or polymers.

In a preferred embodiment, the biodegradable polymer matrix will have degradation rate that is at least equal or faster than the hollow reinforcing fibre. As a result of this surface degradation of the matrix, the porous structure of the device is exposed to the host as the tissue is generated on the surface of the component and progressed along the pores inwardly.

Turning to drawings, Figure 2 illustrates a bioabsorbable intramedullary device (4), for fracture fixation between two sections of bones (5). In a preferred embodiment the intramedullary device (5) is comprised a central stem (8) that is implanted in the prepared shafts (6) of the bone (5). The stem (8) is stiff enough so as to transfer the loads at the fracture site including the loads due to bending moment (M) shear force (V) and torsion (T) to create the required stability for repair of the damaged tissue. In a preferred embodiment the intramedullary device (4), may include an intermediate component (9), which acts as gap filler between the two sections of bone (5). In a preferred embodiment, the intermediate component (9) may be manufactured via a separate manufacturing process with a central aperture so as to allow the central stem (8) to be slotted through it prior or during surgery. The intermediate component may be manufactured of thin slices that are stacked on one another to the required height for filling the gap between the bones as shown in Figure 2. The surfaces (7&10) of the bone (5) and intermediate component (9) bear on one another so as to transmit the compressive forces at the site.

In a preferred embodiment as shown in Fig.3, the stem (8) may be fixed into the bone (5) via the treads (11), which are screwed onto the prepared shaft (6) on one side, while it is press fitted on to the second bone (5). Alternatively the stem (8) of component (4) implanted in the bone on either side of the intermediate component (8), may be treaded (11) such that one side is handed relative to the other. Therefore turning of the component (4) along its longitudinal axis will bring the two fractured part of the bone (5) together. To allow slotting of the stem (8) through the intermediate component (9), the central aperture in the intermediate component (9) is either threaded or large enough for the central pin to slot through.

Figure 3 and 4 illustrate sectional view of the component (4) along its longitudinal axis and A-A as shown in Figure 2 respectively. In a preferred embodiment the composite device (4) may be reinforced by means of discontinuous hollow fibres to form a sandwich structure comprising:

- A core (13) with fibres aligned predominantly in the long axis of the component (4) so as accommodate the required bending and shear stiffness required by the stem (8).
- A first casing (12) encapsulating the core with fibres predominantly aligned transversely to that of the long axis forming a circumferencially reinforced first casing. This will accommodate the required torsional stiffness and strength by the stem (8).
- An intermediate component reinforced with hollow fibre reinforcement oriented in the direction of required tissue regeneration. In the particular case as shown in Figure 2, the hollow reinforcing fibres of discrete length are oriented longitudinally so as to form a porous structure forming a scaffold in the direction of the required tissue regeneration to bridge the fracture. Alternatively, the same fibre arrangement may be obtained using long hollow fibres using alternative manufacturing process such as pultrusion or resin transfer moulding of a performed woven fibre arrangement.

Figure 5, illustrates another embodiment of the present invention in which the proposed device is used for the treatment of degenerative joints in which the cartilage between the two bones are damaged. Current practices for treatment of such condition includes resurfacing of the joints using ceramic or metallic implants (see for example WO 00/45750, Pfaff et. al.). It is however advantageous to repair the damaged cartilage by means tissue regeneration. Referring to Figure 5, the intermediate component (9) of the proposed prosthetic device is formed in the shape of the required bearing surfaces between the two bones (2) with the reinforcing hollow fibres arranged tangentially to the bearing surface. The intermediate component is fixed on one side by means of a stem (8) into the first bone (2) and forms a bearing surface with the second bone (2) on the second side.

In a preferred embodiment, the intermediate component may be seeded with the host tissue in the laboratory prior implantation so as to allow faster recovery after implantation.

I claim:

1. A bioabsorbable composite prosthesis formed by fibre reinforcement of a bioabsorbable polymer matrix by means of bioabsorbable hollow fibres so as to form a porous composite prosthetic device.

2. A bioabsorbable composite prosthesis as of claim 1 wherein the bioabsorbable polymer matrix has a degradation rate greater or equal to the bioabsorbable hollow fibre.

3. A bioabsorbable composite prosthesis as of claim 1 wherein the reinforcing bioabsorbable hollow fibres are substantially long so as to form a composite prosthetic device with continuous porous structure.

4. A bioabsorbable composite prosthesis as of any proceeding claim wherein the fibres are oriented in a given direction using three-dimensional weaving techniques to optimise its stiffness, strength and porosity in a given direction.

5. A bioabsorbable composite prosthesis as of claims 1 wherein the reinforcing bioabsorbable hollow fibres may be of discrete length forming a composite prosthetic device with discontinuous porous structure.

6. A bioabsorbable composite prosthesis as of claims 1, 2 and 5 wherein the orientation of discontinuous bioabsorbable fibres are controlled to optimise the stiffness, strength and porosity of the composite prosthetic device.

7. A bioabsorbable composite prosthesis as of any of above claims wherein the hollow biodegradable reinforcing fibres are coated by osteo-conductive material.

8. A bioabsorbable composite prosthesis as of any of claim 6 wherein the osteo-conductive material is hydroxyapitite.